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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/624,735 | 07/21/2003 | Robin C. Whitmore | CRANIO-42318 | 7156 |

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| EXAMINER | |
|---|---|
| COMSTOCK, DAVID C | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3732 | |

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/624,735 | WHITMORE ET AL. | |
| | Examiner | Art Unit | |
| | David Comstock | 3732 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *21 July 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al. (4,323,326).

Okada et al. disclose a self-drilling screw 1 comprising a body having a head at one end and a tip defining a generally flat cutting edge 8 and 9 at the end of the dual lead thread 6 and 7, respectively (see Fig. 1A; col. 2, lines 10-19 and 30-34; and col. 4, lines 3-5). The dual lead thread 6,7 tapers (as at 3) toward the cutting tip where the pitch widens, and transitions to a straight thread 2 toward the head (see Fig. 1A).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-6 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (4,323,326).

Okada et al. disclose the claimed invention except for explicitly disclosing a head having a recess. It is old and well-known in the fastener art to provide heads with recesses in order to engage a driving tool and facilitate the application of torque to the screw (as evidenced by, *e.g.*, Whitesell, 5,356,253, col. 2, lines 38-41). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the fastener of Okada et al. with a head having a recess in order to engage a driving tool and facilitate the application of torque to the screw. It would have been further obvious to form the screw of titanium alloy, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. It is noted that titanium alloy is a well-known material and is suitable as a fastener due to, for example, its strength, light weight, and non-reactivity or resistance to rust. It also would have been obvious to form the screw to have a diameter of approximately 1.0 to 2.0 mm and a length of approximately 3.0 to 6.0 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, a screw having a diameter and a length, discovering the optimum or workable ranges of these dimensions involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Comstock whose telephone number is (703) 308-8514.

D. Comstock
12 September 2004

EDUARDO C. ROBERT
PRIMARY EXAMINER